

## **Remarks**

### ***Status of Claims***

Upon entry of this amendment, claims 1, 2, 5, 6, 7, 10 and 12 are pending. Claims 1, 2 and 7 have been amended and claim 5 has been previously presented. Claims 6, 7 and 10 are withdrawn, and claim 11 has been cancelled without prejudice or disclaimer. Claim 12 is new.

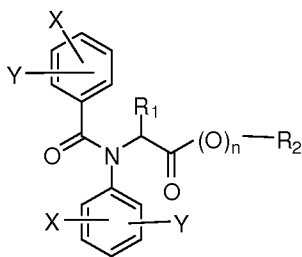
### ***Claims Amendments:***

The amendments to claims 1, 2 and 7 do not add new matter. In addition, new claim 12 does not add new matter.

### ***Claims Rejections: 35 U.S.C. §103(a)***

In the Office Action dated April 22, 2010, claims 1, 2 and 5 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Sogespar (CH 516,523 11-1969, Abstract) or Sogespar (GB 1236091-1971).

The Office Action asserts that Sogespar (CH 516,523 11-1969, Abstract) teaches N-benzoyl-N-phenyl amino acid derivatives having analgesic and anti-inflammatory activity, and further asserts that Sogespar (CH 516,523 11-1969, Abstract) and Sogespar (GB 1236091-1971) teach N-benzoyl-N-phenyl amino acid derivatives of Formula (1):



, wherein X and Y may be halogen, substituted or unsubstituted alkyl, R<sub>1</sub> may be hydrogen and R<sub>2</sub> may be alkyl or cycloalkyl. The Office Action further asserts that “The Examiner considers pharmaceutical compositions of the compounds obvious in view of Sogespar’s teaching of therapeutic benefit. (see Office Action, page 4).

The Office Action asserts that one of ordinary skill in the art “would have found the instantly claimed subgenus obvious over the genus taught by Sogespar in view of the fact that many of the instantly claimed compounds can be found within Sogespar’s genus and have similar activity. Thus one of ordinary skill in the art would have been motivated to make the instantly claimed subgenus of compounds in which R<sub>2</sub> is phenyl with a reasonable expectation of

success in producing a compound having anti-inflammatory activity.” (see Office Action pages 4-5).

The Applicants respectfully disagree and respectfully assert that the compounds of Sogespar do not render the Applicants instantly claimed compounds obvious. The Applicants respectfully assert that the Applicants instantly claimed compounds are LXR agonists; in particular, such compounds activate LXR with an  $EC_{50}$  of  $1 \times 10^{-9}$  to  $1.5 \times 10^{-6}$  M (see p. 45 in the specification as filed). The Applicants respectfully assert that the LXR activating property of the Applicants instantly claimed compounds is not taught or suggested by Sogespar, and assert that the compounds of Sogespar are disclosed as analgesic and anti-inflammatory agents.

The Applicants respectfully assert that the Federal Circuit has held that while “structural similarity between claimed compounds and prior art subject matter....where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness,” a *prima facie* case of obviousness also requires a showing of “adequate support in the prior art” for the change in structure. Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356 (Fed. Cir. 2007) (citing *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) and *In re Grabiak*, 769 F.2d 729, 731-732 (Fed. Cir. 1985)). Clarifying this further, the Federal Circuit has held that a *prima facie* case of unpatentability requires “a showing that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention.” *Id.* (citing *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995), *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992), *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990), *In re Grabiak*, 769 F.2d 729, 731-732 (Fed. Cir. 1985), and *In re Lulu*, 7479 F.2d 703 (Fed. Cir. 1984)). Finally, the Federal Circuit stated that the test for *prima facie* obviousness for chemical compounds “is consistent with the legal principles enunciated in KSR,” and thus, “in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.” *Id.* (citing KSR, 127 S. Ct. at 1731).

The Applicants respectfully assert that the genus of Sogespar does not encompass the Applicants instantly claimed compounds, and respectfully assert that Sogespar does not provide any motivation to make the Applicants instantly claimed compounds. The Applicants further assert that Sogespar does not show adequate support for the change in structure to obtain the Applicants instantly claimed compounds, nor is there any suggest to make the specific molecular

modifications necessary to achieve the Applicants instantly claimed compounds. Specifically, Sogespar does not teach or exemplify compounds wherein X or Y (of Formula (1) above) is a substituted phenyl. In addition, the Applicants respectfully assert that Sogespar does not teach or exemplify how to make such compounds. The synthetic examples of Sogespar appear to only include X or Y as an alkoxy, in particular methoxy or ethoxy, as N-phenyl substituents.

Thus, the Applicants respectfully assert that the Applicants instantly claimed compounds are structurally different and possess properties that are not obvious with respect to Sogespar's compounds, and furthermore, based on the disclosure of Sogespar, one of skill in the art would not have been motivated to make the Applicants instantly claimed compounds as LXR agonists. Therefore, the Applicants respectfully assert that Sogespar does not render obvious the Applicants instantly claimed compounds. Accordingly, the Applicants respectfully request withdrawal of the rejection 1, 2 and 5 under 35 U.S.C. §103(a) as allegedly being unpatentable over Sogespar (CH 516,523 11-1969, Abstract) or Sogespar (GB 1236091-1971).

***Claims Rejections: 35 U.S.C. §103(a)***

In the Office Action dated April 22, 2010, claims 1 and 2 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kontani et al. (EP 1340750-A1-2001) in view of Greene (Protective Groups in Organic Chemistry, 1981, John Wiley & Sons. Pages 158-169).

The Office Action asserts that Kontani (page 22, Table 2, entries 1, 4-6, 8 and 9) teaches compounds (IIIa) which correspond to compounds as instantly claimed except for the ester alkyl group in each. The Office Action further asserts that Kontani teaches (page 8, lines 18-27) use of the acid corresponding to the esters as intermediates in synthesis which have been deprotected. (see Office Action page 5). The Office Action also asserts that Greene teaches (page 158 and 169-169) that simple alkyl esters such as methyl (and presumably ethyl) can be replaced with a tert-butyl group.....Thus, the instantly claimed compounds would have been obvious to one of ordinary skill in the art. (see Office Action, page 6).

The Applicants respectfully disagree and respectfully assert that the compounds of Kontani et al. in view of Greene do not render the Applicants instantly claimed compounds obvious. The Applicants respectfully assert that the Applicants instantly claimed compounds are LXR agonists; in particular, such compounds activate LXR with an EC<sub>50</sub> of  $1 \times 10^{-9}$  to  $1.5 \times 10^{-6}$  M (see p. 45 in the specification as filed). The Applicants respectfully assert that the LXR

activating property of the Applicants instantly claimed compounds is not taught or suggested by the combination of Kontani et al. and Greene, nor by Kontani et al, or Greene alone.

Additionally, the Applicants respectfully assert that the compounds of Kontani et al. are disclosed as anti-viral agents.

The Applicants respectfully assert that the Federal Circuit has held that while “structural similarity between claimed compounds and prior art subject matter...where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness,” a *prima facie* case of obviousness also requires a showing of “adequate support in the prior art” for the change in structure. Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd., 492 F.3d. 1350. 1356 (Fed. Cir. 2007) (citing *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) and *In re Grabiak*, 769 F.2d 729, 731-732 (Fed. Cir. 1985). Clarifying this further, the Federal Circuit has held that a *prima facie* case of unpatentability requires “a showing that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention.” *Id.* (citing *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995), *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992), *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990), *In re Grabiak*, 769 F.2d 729, 731-732 (Fed. Cir. 1985), and *In re Lalu*, 7479 F.2d 703 (Fed. Cir. 1984). Finally, the Federal Circuit stated that the test for *prima facie* obviousness for chemical compounds “is consistent with the legal principles enunciated in KSR,” and thus, “in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.” *Id.* (citing KSR, 127 S. Ct. at 1731).

The Applicants respectfully assert that the compounds of Kontani et al. in combination with Greene do not encompass the Applicants instantly claimed compounds, and respectfully assert that the combination does not provide any motivation to make the Applicants instantly claimed compounds. The Applicants further assert that the combination of Kontani and Greene does not show adequate support for the change in structure to obtain the Applicants instantly claimed compounds, nor is there any suggest to make the specific molecular modifications necessary to achieve the Applicants instantly claimed compounds. Thus, the Applicants respectfully assert that the Applicants instantly claimed compounds are structurally different and possess properties that are not obvious with respect to the compounds resulting from the combination of Kontani and Greene, and furthermore one of skill in the art would not have been

motivated to make the Applicants instantly claimed compounds as LXR agonists. Therefore, the Applicants respectfully assert that the combination of Kontani and Greene does not render obvious the Applicants instantly claimed compounds. Accordingly, the Applicants respectfully request withdrawal of the rejection 1 and 2 under 35 U.S.C. §103(a) as allegedly being unpatentable over Kontani et al. (EP 1340750-A1-2001) in view of Greene (Protective Groups in Organic Chemistry, 1981, John Wiley & Sons. Pages 158-169).

***Allowable Subject Matter***

The Applicants gratefully acknowledge the allowable subject matter.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants believe all claims now pending in this Application are in condition for allowance. It is believed that no fees are necessary in connection with this paper, however if this is incorrect and additional fees are due, or additional extensions of time are necessary to prevent abandonment of this application, then the U.S. Patent and Trademark Office is authorized to deduct any requisite fees from, or deposit any overpayment into, Deposit Account No. **50-1885** referencing docket PAT033827-US-PCT.

If the Examiner believes a telephone conference would expedite prosecution of this application, the Examiner is respectfully requested to contact the undersigned at the telephone number below.

Respectfully submitted,

Date: May 4, 2010

/Daniel E. Raymond, Reg. No. 53,504/

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